

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

All Cases

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

**SAINT THOMAS ENTITIES' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION FOR CONTINUANCE OF
COMMON ISSUE FACT DISCOVERY DEADLINE**

The Saint Thomas Entities¹ file this memorandum in support of their Motion for Continuance of Common Issue Fact Discovery Deadline. By their Motion, the Saint Thomas Entities seek to amend MDL Order # 9 to allow an additional ninety days to conduct common issue fact discovery.

STATUS OF DISCOVERY

This litigation stems from an outbreak of fungal meningitis due to the contamination of pharmaceutical products compounded by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center. (“NECC”). While Plaintiffs have brought suit against the Saint Thomas Entities in an attempt to prove their liability (vicariously) for the *administration* of the steroid by Saint Thomas Outpatient Neurosurgical Center (“STOPNC”), an ambulatory surgery center, it is uncontested that neither the Saint Thomas Entities nor STOPNC had *any role whatsoever* in causing the contamination. Nor is there a shred of proof that the Saint Thomas Entities or STOPNC had any knowledge of any contamination by NECC. It is the Saint Thomas

¹ Saint Thomas West Hospital f/k/a St. Thomas Hospital; Saint Thomas Health; and Saint Thomas Network.

Entities' position that those responsible for the contamination itself are the only parties liable for the injuries caused by this unprecedented outbreak.

The Saint Thomas Entities' efforts to discover the facts of how that contamination occurred and the various parties who bear responsibility for it have been confounded from the beginning by the Plaintiffs' Steering Committee's ("PSC's") attempts to shield the true facts through a mediation process. The documents produced by the mediating parties have slowly trickled out, with documents from some parties having been finally produced for the first time earlier this month (May 2015). Rather than fulfill their discovery obligations, many of the settling parties (like ARL BioPharma, Inc.) maintain that the Saint Thomas Entities are not entitled to any discovery from settling defendants. Yet they have already produced tens of thousands of pages of potentially relevant documents to the PSC. In fact, the Saint Thomas Entities were forced to obtain a court order enforcing what prior orders had clearly said.² Other settling defendants have simply imposed unreasonable limitations on their discovery, forcing significant time and effort to meet and confer to limit the disputes ultimately brought to the Court.

The Saint Thomas Entities are again being confronted with obstructionist tactics aimed at shielding the truth, not discovering it. The parties who are undeniably at fault for the contamination, such as Glenn Chin, who compounded the lot of methylprednisolone acetate ("MPA") at issue, and Barry Cadden, who was aware of fungal blooms at NECC yet permitted

² See *Order on Saint Thomas Entities' Motion to Enforce Court Order Permitting Comparative Fault Discovery Against Settling Parties* (Dkt. No. 1724). Although the PSC and ARL BioPharma ("ARL") have stated that ARL's document production has been made available to the Saint Thomas Entities via the PSC's U.S. Legal document repository (*see, e.g.*, Dkt. No. 1789 at 2), there were technical issues with the load that resulted in the documents only recently becoming available.

the continued production and distribution of MPA, are refusing to be deposed.³ NECC itself, acting by and through a bankruptcy trustee, has likewise refused—on the basis that individuals like Barry Cadden have the discoverable information.⁴ And NECC’s affiliates (like Ameridose) have likewise jumped on board, claiming they have nobody to designate as corporate representatives and accordingly are entitled to “protection” from discovery.⁵

At every turn, the Saint Thomas Entities’ attempts to conduct common issue discovery regarding their comparative fault allegations have been thwarted. Even nonparty depositions originally noticed by some of the Saint Thomas Entities’ co-defendants, such as for witnesses from Scientific Air Analysis and Brigham & Women’s Hospital, have been unexpectedly canceled.⁶ And as this Court is well aware, the FDA has refused to produce a representative for deposition, necessitating a motion to compel by the Tennessee Clinic Defendants.⁷ In fact, scheduling depositions alone has become a monumental task due to the number of witnesses, party, and attorney conflicts.⁸

Despite these formidable discovery hurdles, the Saint Thomas Entities and the Tennessee Clinic Defendants have soldiered on and accomplished a good deal of discovery and case

³ See *Motion for Protective Order and Motion to Quash Deposition Notices to the Invoking Defendants* (Dkt. No. 1823).

⁴ See *Motion of the Chapter 11 Trustee for a Protective Order Pursuant to Fed. R. Civ. P. 26(c) and 45(c) Precluding the Tennessee Clinic Defendants from Conducting a Deposition of New England Compounding Pharmacy, Inc. Pursuant to Fed. R. Civ. P. 30(b)(6) and Quashing Related Deposition Subpoena* (Dkt. Nos. 1810 & 1811).

⁵ See *Motion for Joinder in the Motion for Protective Order filed by Certain Individual Defendants by Ameridose LLC* (Dkt. No. 1824); *Motion for Joinder in the Motion for Protective Order filed by Certain Individual Defendants and Motion for Protective Order by GDC Properties Management, LLC* (Dkt. No. 1826).

⁶ See *Tennessee Clinic Defendants’ Notice of Postponement of Francis McAteer, Michael Cotugno, and Steve O’Neil* (Dkt. No. 1812).

⁷ See Dkt No. 1775. The “Tennessee Clinic Defendants” consist of STOPNC, Howell Allen Clinic, John Culclasure, M.D., Debra Schamberg, Vaughan A. Allen, M.D., Donald Jones, Kenneth Lister, Kenneth Lister, M.D., P.C., and Specialty Surgery Center, PLLC.

⁸ For example, the ARL BioPharma corporate witness is expecting a new baby during the first week of June and accordingly asked to do the deposition later in the month. See May 1, 2015 e-mail from K. Ragosta to A. Schramek and S. Kelly, attached as Exhibit A-1 to the Schramek Declaration.

development from the sources they have been able to access. But despite their reasonable diligence in pursuing discovery, the Saint Thomas Entities will simply not be able to complete Common Issue fact discovery by June 15, 2015, the deadline originally set by the Court.

Below is a summary of the status of discovery with respect to cases and matters of relevance to the Saint Thomas Entities.

| Party/Witness | Written Discovery Served | Written Discovery Status | Deposition Status |
|---|------------------------------|--|-----------------------------|
| Ameridose | RFA, ROGs, RFPs ⁹ | Dispute pending, motion to compel likely | Motion for protection filed |
| ARL BioPharma, Inc. | RFA, ROGs, RFPs | Dispute pending | 6/30/15 |
| Barry Cadden | RFA, ROGs, RFPs | Refused to answer based on invocation of 5th Amendment | Motion for protection filed |
| Lisa Cadden | RFA, ROGs, RFPs | Refused to answer based on invocation of 5th Amendment | Motion for protection filed |
| Edgardo Camacho (Contamination control technician, UniFirst) | | | Scheduling in progress |
| Edwin Cardona (Contamination Control Manager, UniFirst) | | | 6/18/15 |
| Glenn Chin | RFA, ROGs, RFPs | Refused to answer based on invocation of 5th Amendment | Motion for protection filed |
| Rebecca Climer (Chief Communications Officer, Saint Thomas Health) | | | Completed |

⁹ RFA means Requests for Admission, ROGs means Interrogatories, and RFPs means Requests for Production.

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| Clint Pharmaceuticals | Subpoena | Pending | 5/29/15 |
| Carla Conigliaro | RFA, ROGs, RFPs | Refused to answer based on invocation of 5th Amendment | Motion for protection filed |
| Doug Conigliaro | RFA, ROGs, RFPs | Refused to answer based on invocation of 5th Amendment | Motion for protection filed |
| Greg Conigliaro | RFA, ROGs, RFPs | Refused to answer based on invocation of 5th Amendment | Motion for protection filed |
| John Culclasure, M.D. (Medical Director, STOPNC) | RFA, ROGs, RFPs | Completed | Completed |
| Jeff Erickson (Engineering Manager, Liberty Industries, Inc.) | | | Completed |
| Food and Drug Administration | Subpoena | Dispute pending | Motion to compel filed by Tennessee Clinic Defendants / Motion for Protection filed by FDA |
| Steve Higgins (Property Manager, GDC Properties Management, LLC) | Subpoena | Dispute pending | Motion for protection filed |
| Liberty Industries, Inc. | RFA, ROGs, RFPs and subpoena | Refused to answer based on claimed entitlement to subpoena | Scheduling in progress |
| Massachusetts Board of Registration in Pharmacy | Subpoena | Dispute pending | Deposition postponed |
| Medical Sales Management, Inc. / Medical Sales Management SW, Inc. ("MSM") | RFA, ROGs, RFPs | Pending | Pending |

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|---|-------------------------|---|-----------------------------|
| GDC Properties Management, LLC (“GDC”) | RFA, ROGs, RFPs | Dispute pending | Motion for protection filed |
| George Pollick (Chief Engineer, Liberty Industries, Inc.) | Subpoena (to be served) | To be served with subpoena | Scheduling in progress |
| NECC | Subpoena | Motion for protection filed | Motion for protection filed |
| PSC | RFA, ROGs, RFPs | Motion to compel filed by Tennessee Clinic Defendants | |
| Dawn Rudolph (former Chief Executive Officer, St. Thomas Hospital) | | | Completed |
| St. Thomas Hospital | RFA, ROGs, RFPs | Pending ¹⁰ | Scheduling in progress |
| Saint Thomas Health | RFA, ROGs, RFPs | Pending | Scheduling in progress |
| STOPNC | RFA, ROGs, RFPs | Completed | Scheduling in progress |
| Ricardo Santos (Contamination control technician, UniFirst) | | | Scheduling in progress |
| Michael Schatzlein, M.D. (Chief Executive Officer, Saint Thomas Health) | | | Completed |
| Debra Schamberg (Facilities Director, STOPNC) | | | Completed |
| UniFirst | RFA, ROGs, RFPs | Dispute pending | 6/18/15 |

¹⁰ The PSC served a second set of Requests for Production to St. Thomas Hospital (“STH”) and Saint Thomas Health (“STHe”) via electronic mail on May 6, 2015. Accordingly, STH’s and STHe’s objections and responses are due on June 8, 2015. In the event that the PSC takes issue with STH’s and STHe’s objections and responses and chooses to seek court intervention, it would be virtually impossible to reach a resolution by June 15.

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| Victory Heating & Air Conditioning Co. / Victory Mechanical Services, Inc. (“Victory”) | Subpoena | Pending | 6/9/15 |
|--|----------|---------|--------|

The remaining discovery is clearly and highly relevant, and the Saint Thomas Entities would be materially prejudiced if they were not able to obtain it. Consequently, they seek a continuance to insure sufficient time and opportunity to properly complete Common Issue fact discovery in order to prepare their defenses for summary judgment and trial.

ARGUMENT AND AUTHORITIES

A scheduling order may be modified for good cause and with the Court’s consent. *See* Fed. R. Civ. P. 16(b)(4); *Girl Scouts of the USA, et al.*, 383 F.3d 7, 12 (1st Cir. 20014). Good cause exists where a deadline “may not reasonably be met, despite the diligence of the party seeking the extension.” *See House of Clean, Inc. v. St. Paul Fire & Marine Ins. Co.*, 775 F. Supp. 2d 296, 298 (D. Mass. 2011) (citing *Tele-Connections, Inc. v. Perception Tech. Corp.*, Civ. A. No. 88-2365-S, 1990 WL 180707, at *1 (D. Mass. Nov. 5, 1990)). As the chart above and attached declaration demonstrate, the Saint Thomas Entities and other co-defendants such as STOPNC have diligently pursued written and oral discovery against numerous parties and nonparties. *See* Declaration of Adam T. Schramek, filed herewith (the “Schramek Declaration”).

As previously discussed, the Saint Thomas Entities have alternatively asserted in their answers that any liability they may have should be reduced by the comparative fault of other parties and nonparties, including the specific persons and/or entities from which they are seeking discovery. *See* Saint Thomas Entities’ Master Answer to Complaint (Dkt. No. 1464). The relevance and necessity of the discovery at issue includes, without limitation, the following:

- The “fungal blooms” that continued to occur after UniFirst “cleaned” the NECC facility, despite the fact Barry Cadden brought the contamination to UniFirst’s attention. *See* Exhibit A-2 to the Schramek Declaration. The fungal contamination ultimately made its way into the lots of MPA distributed to health care providers and patients. Evidence from UniFirst, its contamination control manager, and the technicians actually cleaning the NECC facility are needed so the jury may properly allocate fault for the contamination.
- The design and installation by Liberty of certain cleanroom components that the Saint Thomas Entities contend contributed to the fungal problem at NECC. Current Liberty employees have claimed they were not involved in the relevant decisions, thus requiring discovery from a former employee.
- The circumstances under which Ameridose and Liberty designed the NECC cleanroom and the circumstances under which Ameridose turned it over to NECC. Evidence from Liberty, former Liberty employee George Pollick, and Ameridose is needed so the jury may properly allocate fault for the contamination.
- The circumstances under which the NECC cleanrooms continued to have pressurization and humidity defects resulting in non-compliance with required standards, despite various parties’ efforts to correct them. Evidence from Victory, NECC, and Ameridose is needed so the jury may properly allocate fault for the contamination.
- The long history of maintenance and repairs needed at the NECC facility, including problems in the NECC cleanrooms. Evidence from GDC and current

employee Steve Higgins is needed so the jury may properly allocate fault for the contamination.

- The representations and marketing strategies of MSM, which falsely stated that the NECC facility and its products were compliant with all required industry standards. Evidence from MSM and its sales force is needed so that the jury may properly allocate fault for MSM's misrepresentations.
- The regulatory history of NECC and Ameridose by state and federal regulators. Evidence from the FDA and the Massachusetts Board of Registration in Pharmacy is needed so that the jury may properly allocate fault for the failure of regulators to ensure that NECC compounded medication free from contamination and in compliance with applicable state law.
- The testing performed on the MPA by ARL BioPharma, which was hired by NECC to make sure the product it was distributing was not contaminated. Evidence from NECC, Ameridose, and ARL BioPharma is needed so the jury may properly allocate fault for the contamination.
- The oversight and management of NECC by its owners, directors, and managers. Evidence from the Caddens, Conigliaros, and Mr. Chin is needed so the jury may properly allocate fault for the contamination.

Not only is the remaining discovery needed essential to the Saint Thomas Entities' defenses, but neither the PSC nor any other party will be prejudiced by a continuance. No trial dates have been set, and the Saint Thomas Entities are not by this motion seeking to move any other discovery date. Instead, they simply seek three more months so that they may obtain the

discovery already requested—including time for the resolution of motions to compel as may be necessary—and any additional matters that may arise from such discovery.

In conclusion, despite their reasonable diligence, the Saint Thomas Entities need additional time to develop evidence that is not only relevant, but essential to their defense in these proceedings. The continuance is not sought for the purposes of delay, but so that the Saint Thomas Entities will be able to defend themselves and justice may be done. Accordingly, they ask the Court to continue the common fact issue discovery deadline for 90 days.

Dated: May 13, 2015

By their attorneys,

/s/ Sarah P. Kelly

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CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing this 13th day of May, 2015.

/s/ Sarah P. Kelly

Sarah P. Kelly